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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61N 5/10, A61F 2/06, C25D 1/08 — A2

(11) International Publication Number: **WO 00/32273**

(43) International Publication Date: 8 June 2000 (08.06.00)

(21) International Application Number: PCT/US99/28274

(22) International Filing Date: 30 November 1999 (30.11.99)

(30) Priority Data:
09/201,972 1 December 1998 (01.12.98) US

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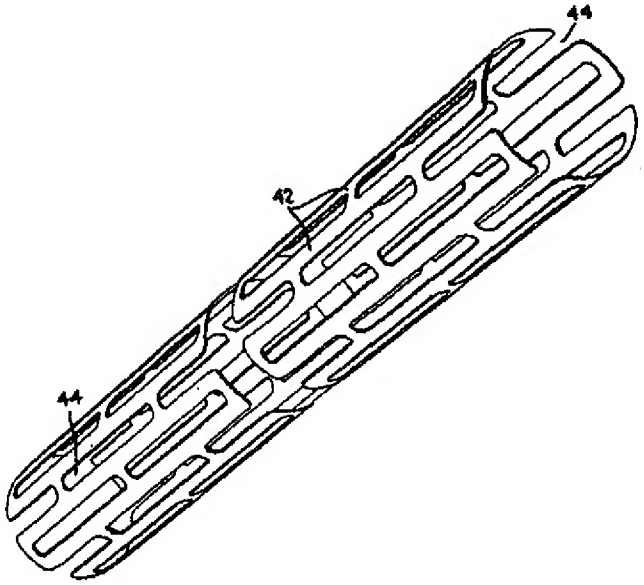
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: UNIFORM EXPANSION RADIOACTIVE STENTS



(57) Abstract

This invention is directed to a radioactive expandable stent (See Fig. 2) useful for implantation into an artery or the like. In one aspect of this invention, the stents can be made into radioactive beta emitters by direct exposure to thermal neutrons. The present invention also provides for a stent pattern (See Fig. 5) comprised of one or more logitudinal members (46) connected by a plurality of flexible circumferential bands (48). The flexible circumferential bands (48) are connected to the longitudinal members (46) so as to allow for an expansion in circumference of the stent without a corresponding decrease in length of the stent. In one preferred embodiment, the stent is formed by an electroforming process and is comprised of gold.

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UNIFORM EXPANSION RADIOACTIVE STENTS

The U.S. Government has rights in this invention pursuant to contract number DE-AC04-76-DP00613 with the United States Department of Energy.

Background of the Invention

The present invention relates to a novel process for producing stents and the product of that process. More particularly, the present invention relates to a process for electroforming stents, for exposing a photoresist pattern on cylinders, for producing radioactive stents by exposing stents to thermal neutrons, and to the pattern of the stents.

Expandable hollow sleeves used as intravascular endoprosthesis, commonly called stents, are utilized as reinforcements for organ parts in a variety of situations. Typically, they are utilized to support coronary arteries after angioplasty, a process which is used to open clogged arteries. In a typical angioplasty operation, a thin flexible tube, called a catheter, is used to insert a tiny balloon, referred to as an angioplasty balloon, along an artery until it is in a desired position. Once the balloon is in position in an artery, it is inflated so as to open and enlarge the artery, after which the balloon is deflated and removed. This procedure is known to efficiently reopen clogged arteries. However, the arteries thus opened have a tendency to shrink or close, a process known as restenosis. Stents are often utilized to hold the arteries open by mechanically supporting the inside of the artery.

A stent used for angioplasty and similar procedures typically is a small, lattice-like tubular structure, on the order of .16 cm (1/16 inch) in diameter and 1.3 cm (1/2 inch) long. The lattice which forms the tube appears like thin metal wires woven together. The tube lattice is a deformable mesh which permits expansion in the stent's radial, or circumferential, dimension. In use, the stent is first inserted over an uninflated angioplasty balloon and then both the stent and balloon are inserted by means of a catheter into the patient. The balloon is inflated, expanding the stent and the artery, after which the balloon is deflated and removed. The expanded stent remains expanded to prevent closure of the artery.

Because of their use internal to the body, stents are subject to a number of rigorous requirements. The stent material must be biocompatible, so that it is neither absorbed by the body nor rejected by the body. Body fluids are highly corrosive to many metals. Thus the stent material must be corrosion resistant to blood and other body fluids. Also, the body's immune system attacks foreign objects. To reduce the risk of such attack, the material of the stent must be inert. The stent material also must be mechanically suitable. It must be sufficiently ductile to be deformed into an expanded condition when the balloon is

inflated. It must also be sufficiently rigid to maintain its shape when the balloon is deflated and the artery or the like begins to return to its former size. Because these material constraints vary depending upon the particular application, there is a need for stents to be produced from a variety of metals. Also, blood can easily be damaged by passage through rough, irregular structures and form clots which could clog the artery. Thus, stents must have a very smooth and regular internal surface.

Radiation of the artery wall following balloon angioplasty has been shown to reduce restenosis. One method of providing such post-angioplasty radiation is through the use of a radioactive ribbon or radioactive beads that have been activated to deliver high intensity gamma radiation. The radioactive ribbon or bead is inserted into the artery for a few minutes and removed, thereby delivering a fairly uniform dose of radiation to the artery wall. However, the use of high intensity gamma radiation may penetrate and damage tissue surrounding the artery. Further, the use of high intensity gamma radiation requires the use of strict precautions by operating room personnel.

To overcome the shortcomings associated with high intensity gamma radiation, much research has been directed to providing post-angioplasty radiation by transforming traditional stainless steel stents into low level beta emitters. The lower activity stents are inserted into the artery, expanded and left in the artery after the operation to provide a low level of radiation over a period of time. Stainless steel stents are generally made radioactive by exposure to deuterons and protons or by direct bombardment with phosphorous 32 in a cyclotron. The methods of preparing such stents can be complicated and costly, and access to appropriate cyclotrons is limited. Therefore, such radioactive beta-emitting steel stents primarily have been developed and used for research purposes and such beta-emitting steel stents have not been produced on a commercial scale.

There are a variety of existing methods for forming stents. In one method, stents have been made using a high power laser to machine slots in a stainless steel tube. This entails using a laser to melt away unwanted portions of the tube, forming a stent lattice. However, accurately positioning and machining a tube in this manner is difficult and the process typically requires manual inspection and processing after the laser machining is performed to remove metal fragments, commonly called slag, from the interior bore of the stent. Slag can take the form of sharp projections that can inhibit blood flow and trigger clotting. Chemical or mechanical removal of slag and inspection to insure a smooth, clean

inside surface complicates the laser fabrication process and makes quality assurance and quantity production difficult.

In another method, as noted in U.S. Patent No. 5,421,955, which is incorporated herein by reference, a mask of acid resistant material is coated onto a metal tube after which a pattern is formed in the mask by use of a laser. A stent is then formed by immersing the masked metal tube into an acid or other metal etching fluid, thus etching away the unmasked material. A limitation of this method is that the etching material eats away at portions of the tube alongside the mask-protected material, allowing the etching material to move under the mask a distance approximately equal to the tube wall thickness. As a result, the cross-section of stent elements formed by etching tends to be nonrectangular and have thin sharp edges. Further, such stents tend to have unpredictable variations in lattice pattern as a result of variations in the amount of material etched away under the mask. The sharp edges and unpredictable patterns created in this process can impede blood flow and damage the blood. Moreover, the etching process limits selection of tube materials to those amenable to etching and also limits tube selection to those with wall thickness which will accommodate the etching process.

Because of the variations inherent in existing processes for producing stents, significant amounts of post-production inspection are required to assure that the required quality is achieved. As a result, existing processes generally require substantial amounts of manual labor to produce completed stents, which results in a relatively high production cost.

Other common problems with existing stents arise from the simple lattice pattern of the stents. Specifically, when most existing stents are expanded in circumference, such as by the angioplasty balloon within the artery, a corresponding decrease in the length of the stent results. This shortening presents difficulties in the use of existing stents in that the precise amount of shortening may be difficult to predict, making selection of the appropriate stent length for a given patient difficult. Moreover, this shortening effect may cause damage to the artery as the stent drags against the artery wall as the stent shortens. Further, the simple lattice patterns tend to be inflexible, making placement of the stent and conformation of the stent to the natural curves of arteries and veins difficult.

Summary of the Invention

It is thus an object of this invention to devise a process which is capable of producing consistently high quality stents having uniform and predictable geometry and material properties.

It is a related object of this invention to produce a stent which allows increased flexibility in selection of type of materials for forming stents along with increased flexibility in selection of stent geometry including wall thickness, length, diameter and pattern.

It is another object of this invention that stent surfaces are controlled to reduce or eliminate sharp edges and protrusions which can disrupt blood flow.

It is a related object of this invention to be able to produce stents in an efficient and reliable manner in a process suitable for quantity production at a reasonable cost.

It is a further object of this invention to provide a stent that will not shorten in length in response to an increase in circumference.

It is a related object of this invention to provide a stent that is highly flexible so that it can be maneuvered into position beyond tight bends and conform to natural curves in veins, arteries, and the like.

It is another object of this invention to produce a radioactive stent through thermal neutron activation.

These and other objects of the invention will be made clear from the following specification, drawings, and claims.

The present invention is a unique process for electroforming stents and the product of that process. In the basic process of the present invention, stents are formed on an appropriate sacrificial mandrel, for example copper or similar wire or tube, in a series of steps. First the mandrel is coated with a resist, which is a coating that can electrically isolate portions which it covers. The resist-coated mandrel is exposed to a light source sufficient to form a stent image on the resist, and is developed to expose portions of the mandrel. The exposed mandrel surface is then electroplated with an appropriate metal such as gold, gold alloy, or nickel to a thickness equal to the desired stent wall thickness. Subsequently, the mandrel is dissolved in an etching solution or the like leaving a completed stent. The stent image and mandrel circumference may correspond to the stent in the expanded state or the stent in the unexpanded state or any circumference and pattern between the two. If the stent is electroformed in the expanded state it may be crimped to its unexpanded state onto the angioplasty balloon or it may be crimped prior to being placed on the balloon.

The present invention process produces a stent in a wide variety of desirable materials and configurations. The process is suitable to provide basically any desired size of intervascular stent. Because the stent is formed on the surface of a mandrel, the interior surface is readily made very smooth. Because the present invention process uses high accuracy imaging techniques, stents may be formed in a very repeatable, controllable manner resulting in uniform and predictable stent geometry at a reasonable cost.

In one aspect of this invention, stents can be made radioactive by exposing the stent to thermal neutrons. Thermal neutrons will be recognized by those of ordinary skill in the art as neutrons in equilibrium with the thermal motion of matter at room temperature. Thermal neutrons have an average kinetic energy of about 0.025 eV, corresponding to a speed of about 2200 m/sec. Nuclear fission produces neutrons with high energy and speed. Thermal neutrons may be produced from high speed neutrons by slowing the high speed neutrons through collisions with nuclei. In a fission reactor, high energy neutrons are produced by the fission process, and the neutrons are slowed to thermal velocity by collisions with the moderator nuclei in the reactor.

In addition to the basic biocompatible requirement for stent materials, a radioactive stent should be comprised of a material that will produce a level of beta radiation sufficient to concentrate the therapeutic action of the radiation in the tissue in close proximity to the stent. It is also desirable that the radiation decrease with time as the body heals so that when the healing is complete, the radiation is no longer present. Ideally the process for making the stent radioactive is readily available on a commercial scale and can be repeated to reactivate the stent if the radiation level falls below the desired therapeutic level before use.

Gold is the preferred metal for forming the radioactive stents of the present invention and preferably the stents are formed by the electroforming process of the present invention. However, stents made by other methods (e.g., laser cutting stents from gold tubes or by welding gold wire) and made of other suitable metals may also be made radioactive by thermal neutron exposure in accordance with the present invention. The time of exposure and level of neutron flux in the reactor should be sufficient to produce a stent which will emit the required therapeutic level of beta activity when inserted into the artery. The stents may be activated to initially produce higher levels of beta radiation to compensate for the reduction in activity that will occur during shipping and storage, such that at the time the stent is inserted into the artery, the level of beta emission is at the desired therapeutic level.

The present invention also provides for a stent pattern which will allow the stent to increase in circumference without decreasing in length, while providing a stent which is highly flexible, especially along its longitudinal axis. The present invention stent pattern is comprised of one or more longitudinal members that extend the length of the stent, connected by a plurality of flexible circumferential bands that deform when the circumference of the stent is expanded. The flexible circumferential bands are connected to the longitudinal members so as to allow for an expansion in circumference without a corresponding decrease in length of the stent. The flexible circumferential bands are preferably configured in a wave pattern or in a pattern of connected closed loops, for example ovals or diamond-shaped loops, with longitudinal members connected to the band at identical points in the repeated wave or loop pattern. Various other configurations of flexible circumferential bands are consistent with this stent pattern. In another preferred embodiment, the longitudinal members are configured to resist extension and contraction in the direction along the stent axis and to contain U-shaped loops to add flexibility along the longitudinal axis.

Brief Description of the Drawings

Fig. 1 is a block diagram of a preferred embodiment of a stent manufacturing process.

Fig. 2 is an oblique perspective view of one embodiment of a completed stent of the present invention.

Fig. 3 is a view of a rolled out stent pattern of Fig. 2.

Fig. 4 is a pictographic block diagram of a preferred embodiment of a continuous mode stent manufacturing process.

Fig. 5 is a view of a rolled out stent pattern of another embodiment of the present invention.

Detailed Description and Preferred Embodiments

The following discussions of embodiments of this invention are instructive to describe workable configurations, but are not intended to limit the scope of the invention. In particular, various materials, use of resist or photoresist, various exposure methods, number of optic fibers, and similar details which are shown in the figures and described herein are exemplary embodiments illustrative of the various configurations within the scope of the current invention. It is noted that the present invention stent manufacturing process may be implemented as either a batch process or a continuous mode process. A batch mode process is one in which a plurality of items are processed simultaneously. In a stent batch process, a

plurality of individual lengths of mandrel material with multiple stent patterns may be processed simultaneously. In a continuous mode process, a plurality of parts is produced sequentially in a continuous fashion. In a continuous process of the present invention, mandrel material, such as wire, moves from a source such as a large roll of wire and is directed through a series of processing stations to continually form completed stents. The discussion below exemplifies the typical considerations of both batch as well as continuous mode process.

Figure 1 shows a basic series of process steps of a preferred embodiment for producing stents according to the present invention. In this embodiment, a liquid resist which is photoimagable, called photoresist, is applied at an application station 01 to a mandrel material which is dried at a drying station 02 to form a photoimagable film on the surface of the mandrel. The photoresist-coated mandrel is then exposed to a desired stent image at an exposure station 03.

Figure 2 shows an oblique view of a typical stent image which could be formed on a mandrel.

Figure 3 shows the pattern of Fig. 2 rolled out flat for clarity. This pattern is preferably used on a mandrel having a diameter equal to an unexpanded stent. Other patterns could be used to form the stent at a large diameter that may be mechanically crimped to a smaller diameter before use. Forming the stent at a diameter larger than the delivery size allows for a larger fraction of the surface area of the stent to be metal, which provides additional support for the artery or other vessel. The mandrel with the exposed photoresist is passed through an appropriate chemical bath to develop the photoresist at a developing station 04. Developing of the exposed photoresist removes portions of the photoresist from the mandrel. As is known in the plating arts, depending upon the type of photoresist selected, either portions of the resist which were exposed to light are removed or, alternatively, portions of the resist which were not exposed are removed. Either type of resist is suitable for the present invention. Thus, after the photoresist is developed, the desired stent material is electroplated onto exposed portions of the mandrel at a plating station 05. Thickness of the stent thus electroplated is controlled by factors well known in the electroplating arts. Following electroplating, the electroplate solution is rinsed off of the mandrel and stent at a rinsing station 06. Next the remaining photoresist is removed (stripped) at a stripping station 07 by an appropriate chemical after which the mandrel and stent are rinsed at station 08 to remove photoresist stripping chemicals. The mandrel is removed by dissolving it in an

appropriate etching solution at etching station 09, after which the completed stent is rinsed and dried at station 10.

Figure 4 shows a pictographic representation of a preferred embodiment of the present invention process which includes features allowing production of stents in a continuous mode process. For clarity, items which serve functions similar to stations 01 through 09, respectively shown in Fig. 1, are numbered 11 through 19 in Fig. 4. In this embodiment, a roll 20 containing wire or tube with suitable characteristics as discussed herein to be used as a mandrel is configured so that a continuous length of the mandrel 21 may be pulled from the roll 20. The mandrel 21 is trained over rollers 22 and caused to pass through a tank of liquid photoresist 11. Next, the resist-coated mandrel 21 is moved past a heat lamp 12 or similar drying device and then past an exposure system 13, and through a resist development tank 14. The development tank contains a developing spray 24, a rinsing spray 26, and a drying station 28. At this point, the resist coating on the mandrel 21 has been removed selectively from the areas where plating is to occur. The mandrel 21 next passes through a plating tank 15, where the desired stent material is plated. The plated mandrel 21 then moves through a rinse spray 16, a resist strip tank 17, another rinse spray 18, and into an etch tank 19 where the mandrel 21 is dissolved. The completed stents collect in the etch tank 19 and are subsequently removed for rinsing and drying. The mandrel 21 preferably is pulled at a constant speed by pinch rollers 29 driven at the same speed as other rollers in the process. The time the mandrel is at each processing station (e.g., drying and electroplating) may readily be controlled by adjusting the length of mandrel portion at a given station or tank. The preferred exposure system 13 of this embodiment comprises a controller 40, which may be a computer or similar device, operably connected to light emitting diodes (LEDs) 36 that are coupled to optic fibers 38. The optic fibers 38 are routed to a mounting fixture 32. The optic fibers 38 and fixture 32 together form an exposure ring 30 which surrounds the mandrel. The optic fibers 38 are used to direct light to the resist coating on the surface of the mandrel 21 and thereby create a stent pattern in the resist.

Stent material is selected for biocompatibility and mechanical characteristics. It must be sufficiently ductile to be radially, or circumferentially, expandable to form an appropriate intra vascular endoprosthesis and sufficiently rigid to hold its shape once the expansion force is removed. It must also be sufficiently inert to be biocompatible and resistant to etching solutions. Gold and various gold alloys generally satisfy these requirements because they are generally inert and resistant to corrosion from bodily fluids

and, also are resistant to a wide variety of etching solutions. Generally any electroplatable materials could be formed into stents in the present invention process. Other metals which have specific beneficial characteristics as stent materials include silver, nickel, platinum, rhodium, palladium, tin, iron and various alloys of these metals. It is anticipated that high gold, platinum, or nickel content alloys with from about 95 to about 100 percent content of such metals would produce stents with highly desirable characteristics. Selection of particular materials for a specific application would be based primarily upon biocompatibility and mechanical characteristics as discussed herein. Specialized materials, such as radioactive isotopes, may also be incorporated into the present invention stent to gain specific medical benefits. Radioactive isotopes have been shown to reduce restenosis. Such materials may either be incorporated into the original electroformed stent or the completed stents could be electroplated with additional layers of material to change the final mechanical and/or medical characteristics of the stent. Further, if the stent is comprised of an appropriate material, the completed stent may be exposed to thermal neutrons to convert the stent into a radioactive stent as described below. The stents may also be coated with an inert organic coating to isolate the stent from the body chemistry. Thus, it may be seen that the present invention process allows great latitude in the selection of desirable stent materials and characteristics.

Mandrel material selection is influenced by the availability of etchants that could dissolve the mandrel without damaging the selected stent material. Conductivity, ductility, and compatibility with the electroplating process also influence mandrel material selection. For example, in applications in which gold or gold alloys are used as stent materials, a wide range of materials are suitable for mandrel material because of gold's resistance to a wide variety of etchants. Copper is a preferred mandrel material because it is highly conductive, is easily electroplated, and is commercially available in a wide variety of manufactured wire and tube sizes. In comparison, if nickel is selected as a stent material, aluminum would be a more preferred mandrel material than copper because aluminum can be more easily be selectively dissolved in the presence of nickel than can copper. Thus, various materials could be utilized to form the mandrels of the present invention process based upon parameters familiar to one skilled in the art. Basically, any sufficiently ductile and electrically conductive material which is acceptable as an electroplating base material that can be easily etched away from the electroformed stent could be utilized. Thus, usable materials include copper, aluminum, nickel, steel, and the like. The preferred shape of a mandrel will generally be circular to best form a circular stent, although it would be readily apparent to one

skilled in the art that a variety of other shapes could be made by the present invention process. In one embodiment of the present invention, a balloon catheter may be directly used as a mandrel. In this embodiment, the catheter is prepared by coating it with an appropriate electroconductive material. Using the steps of the present invention process, stents then may be directly electroplated on the balloon catheter.

Two basic types of resist material are suitable for use in this invention, i.e., photoimageable resist, called photoresist and resist which is not photoimagable, which will be referred to as nonphotosensitive resist. As used herein, the term resist refers to a substance which is used to form a dielectric layer to prevent electroplating of materials and which may be selectively removed. In use, photoresist is exposed to an appropriate frequency and pattern of light and, then, developed. Portions of the mandrel area to be electroplated are uncovered by the developing process. Photoresist generally is the preferred resist material for use in the present invention process, because of its commercial availability and ease of use. As discussed herein, there are a number of photoimaging systems available for use with photoresist. Nonphotosensitive resists may also be utilized in the present invention. In using nonphotosensitive resist, a high intensity laser light is used to ablate the resist in order to expose the mandrel. Although such systems are feasible, generally it is more difficult to control and implement high intensity imaging systems as compared to low intensity systems. The particular resist or photoresist selected must be compatible with the selected mandrel, plating baths and, also, must be compatible with the exposure methods to be utilized.

A variety of methods could be used to expose the stent image on the photoresist coated mandrel. One preferred embodiment of an exposure method is shown pictographically in Fig. 4. In this embodiment, a plurality of optical fibers 38 are used to direct light to an exposure ring 30, through which ring a photoresist-coated mandrel 21 is passed. The exposure ring includes a mounting fixture 32 on which a plurality of optic fibers 38 or other light-conducting members are mounted. The exposure ring advantageously is located in a plane perpendicular to the axis of the mandrel 21. The optic fibers 38 are mounted in a spaced relation around the periphery of the mounting fixture 32 and are configured to direct light toward the center of the ring onto the mandrel 21. In this manner, a stent pattern can be exposed on a moving mandrel by selectively passing light through the multiple optic fibers 38 to create a stent pattern. For example, 24 optic fibers evenly spaced around an exposure ring 30 would each cover 1/24 of the circumference of the mandrel or 15 degrees of arc. By controlling light from each fiber at the appropriate time while the mandrel

is moved, a stent image with 24 alternating bars and spaces, such as is shown in Figs. 2 and 3, could be exposed on the surface of the mandrel.

Optic fibers for exposing the resist need not be located in one plane along the axis of the mandrel. Rather, optic fibers may be staggered along the travel of the mandrel and, by switching the light to individual fibers on or off at the appropriate time as the mandrel passes, the entire outer surface of the mandrel may be exposed. In another embodiment, bundles of smaller fibers may be used to provide a line source of light, which may be advantageously used to expose finer patterns due to a more uniform exposure of the resist. Further, bundles of small optic fibers provide a more uniform light than a single circular light from a single fiber. Such bundles may be square or rectangular. Alternatively, fibers or light pipes with noncircular cross sections may be used to produce a variety of light and exposure patterns. For example, a narrow rectangular cross section at the exit end of an optic fiber approximates a line source which produces uniform light intensity, and, thus, uniform exposure. In comparison, a larger rectangular cross section at the exit end of a fiber may be used to flash expose larger areas of a stent pattern. Similarly, a tapered filament or light pipe may be used to funnel light from a large entrance to a small exit area, concentrating available light to accelerate exposure.

As is depicted in Fig. 4, one preferred light source consists of an appropriate number of light emitting diodes (LEDs) 36, for example blue LEDs, each with an associated optic fiber or fiber bundle 38 to bring light to the photoresist-coated surface of the wire mandrel. Because LEDs may rapidly be cycled on and off electronically, computer control of amplified signals to power LEDs at the appropriate times may be used to trace the stent pattern on the moving mandrel. Another option for light sources is low power lasers. Such lasers with a wavelength output appropriate for exposing the photoresist could be used to directly expose the photoresist or could be used to inject light into each fiber or bundle of fibers 38. An exposure system using lasers in place of LEDs would be capable of very high writing speeds (stents exposed per unit of time) because the higher intensity of the light available from such lasers exposes photoresistive materials more rapidly than lower intensity sources, such as LEDs. In another embodiment, an optical fiber exposure system uses a continuous light source, such as a high pressure mercury vapor lamp with optical fibers and mechanical shutters to generate light at the appropriate area and time in the appropriate fiber to expose the stent pattern.

Optical fiber exposure systems as described above are well suited for making stents in a continuous mode. Various other exposure methods, some of which are known in the art, readily could be used in the present invention process. Optical fiber exposure systems can expose fixed lengths of resist coat wire for subsequent batch processing. For example, a cylindrical photomask may be used with a flash lamp exposure to form an image of a stent on a photoresist-coated mandrel. After each image is thus formed, the mandrel is indexed to the next unexposed section of mandrel. Thus, using intermittent linear motion of the mandrel, stent images are produced along the length of the mandrel in the photoresist.

In a specific embodiment, a novel exposure method well suited for making stents in the batch mode uses a thin flexible photomask through which one or multiple stent images are exposed on a length of resist-coated mandrel material. The flexible photomask is threaded between two parallel cylindrical support rollers forming a loop on one side of the support rollers. The resist-coated mandrel is placed in the loop with the axes of all three cylinders being parallel. The width of the gap between the support rollers is smaller than the diameter of the mandrel. The flexible photomask is placed in tension and pulled a distance equal to the circumference of the mandrel causing the mandrel to rotate one revolution. Using a cylindrical lens, light is focused on the center of the mandrel. The stent image on the photomask is produced to match the circumference of the mandrel. To expose a mandrel, the exposure light is turned on while the mandrel is rotated at a constant speed through one revolution. After exposure, tension in the mask is released, and the mandrel is removed from the mask loop. The exposed mandrel is then processed through the steps described above.

It will be obvious to one skilled in photolithography and automation that various optical or video alignment aids and various mechanical systems can be used to control rotation speeds and exposure. Also it will be obvious that one exposure system can accommodate a wide range of mandrel diameters and stent patterns by using an appropriate photomask. The basic cylindrical exposure system can obviously be scaled to image smaller or larger cylinders. It can be used to image resist on a tube for building stents, or other cylindrical devices, by etching. Imaging photoresist or larger cylinders has application in the printing or engraving industry.

As noted herein, Figs. 2 and 3 depict a standard stent pattern such as is known in the art. The stent pattern shown can readily be made from the 24 optic fiber exposure system discussed above. Figures 2 and 3 show 24 bars 42 and spaces 44 around the circumference of the stent. Thus, the pattern shown may simply be made by selectively

operating LEDs or the like as a resist-coated mandrel is moving past an exposure ring 30. As is apparent to one skilled in the plating arts, the present invention process can be used to produce virtually any stent pattern desired by using the various exposure systems available.

Fig. 5 depicts an additional embodiment of a stent of the present invention comprising a novel pattern of longitudinal members 46 and flexible circumferential bands 48 connected such that a circumferential expansion will not result in a shortening of the length of the stent. In Fig. 5, the stent pattern is depicted as a two-dimensional pattern in the form that would result if the stent was cut lengthwise to form edges *a* and *b* and rolled out. The stent actually exists as an essentially cylindrical-shaped tube in which the stent pattern forms the exterior of the stent.

For purposes of description, the axis extending parallel to edge *a* will be referred to as the longitudinal axis, with the length of the stent extending along the longitudinal axis. One or more longitudinal members 46 extend the length of the stent, parallel to each other and to the longitudinal axis of the stent. Longitudinal members 46 are connected by a plurality of continuous flexible circumferential bands 48 extending along the exterior of the stent circumferentially between adjacent longitudinal members. The longitudinal members 46 and flexible circumferential bands 48 are configured to work together to provide support to the vein, artery or other vessel and to essentially eliminate longitudinal shortening of the stent during circumferential expansion. To this end, each such flexible circumferential band 48 preferably connects to adjacent longitudinal members 46 at connection points 52, where each such connection points 52 for a given band is at essentially the same distance along the longitudinal axis of the stent. See points labeled M and N in Fig. 5. When only one longitudinal member 46 is present in the stent pattern, flexible circumferential band 48 connects to the longitudinal member 46 at only one point on each flexible circumferential band 48.

In a preferred embodiment, each longitudinal member 46 contains a plurality of flexible longitudinal loops 50, preferably U-shaped, which extend along the exterior of the stent perpendicular to the longitudinal axis. Longitudinal loops 50 extend between flexible circumferential bands 48 in a direction generally parallel to the flexible circumferential bands 48. Preferably, one longitudinal loop 50 extends between each two flexible circumferential bands 48. Longitudinal loops 50 facilitate bending of the stent, and as a result, the stent formed of this pattern of the present invention is highly flexible along its longitudinal axis.

The flexible stent formed of this pattern of the present invention can be maneuvered beyond tight bends in the artery or vessel and can conform to natural bends in the vessel.

Flexible circumferential bands 48 are configured to deform when the circumference of the stent expands, such as when the angioplasty balloon is inflated within the stent in an artery, without a corresponding shortening of longitudinal members 46. When the angioplasty balloon is inflated, the stent expands in circumference. The expansion of the balloon places the flexible circumferential bands 48 in tension. The tension deforms the waves or loops that comprise the flexible circumferential bands 48. The waves or loops straighten or flatten as the circumference is forced to expand. Because each flexible circumferential band 48 is only connected to each longitudinal member 46 at one point and is only connected to the longitudinal members 46 at equivalent positions along the longitudinal axis, the longitudinal members move farther apart during circumferential expansion but do not change their basic shape or length. Explained another way, because the connection points 52 for a given band 48 all lie in the same plane formed perpendicular to one point on the longitudinal axis, vector forces generated by tension in such band 48 must also lie in that plane. Therefore, no vector forces are imposed along the longitudinal axis direction and no change in longitudinal length occurs. Thus, the stress of the expansion is taken up by the flexible circumferential bands 48 without imposing longitudinal stress. Circumference expansion will therefore not place a significant stress on longitudinal members 46 or longitudinal loops 50 and as a result will not significantly affect the length of the stent. This feature and the overall flexibility of the design will allow the stent to reach the desired expansion with a minimum of sliding between the vessel wall and the stent, thus reducing trauma to the vessel wall. Of course, free, simple cylindrical expansion of the stent, as described above, will not be the case in the body, but the ability of the stent to expand in circumference without a decrease in length will reduce trauma to the vessel being supported.

As discussed herein, longitudinal members 46 and flexible circumferential bands 48 may be described accurately either as continuous longitudinal members 46 connected by flexible circumferential bands 48 or as continuous flexible circumferential bands 48, connected by longitudinal members 46. Either description is intended to describe the present invention.

Flexible circumferential bands 48 consistent with the present invention may be configured in a variety of shapes. In one preferred embodiment, shown in Fig. 5, the flexible circumferential bands 48 preferably consist of a wave pattern. The wave pattern may be

selected from the group consisting of sinusoidal, saw-tooth, rectangular and square wave shapes or any other wave shape. Of course, because the pattern forms the exterior surface of the stent, the waves extend along the exterior of the stent. Sharp corners in the filaments that form the waves that form the flexible circumferential bands 48 concentrate the stress at the sharp corners on the flexible circumferential bands 48 such that permanent plastic deformation results. Such plastic deformation is desirable to prevent the stent from springing back to its unexpanded configuration when the pressure causing expansion is removed.

Preferably, each longitudinal member 46 is connected to a given circumferential band 48 at the same location on each wave, for example all connections on a given band may be at a wave peak. In other words, longitudinal members 46 are connected to a given circumferential band 48 at connection points 52 located one wavelength, or an integer number of wavelengths, apart. In the embodiment shown in Fig. 5, connection points 52 between longitudinal members 46 and three circumferential bands 48 are located at the peak of each wave and the connection points 52 between longitudinal members 46 and the other three circumferential bands 48 are located at the valley, i.e. negative peak, of each wave on the band. In addition, all connection points 52 on a given band are approximately the same distance along the longitudinal axis. In this manner, the portion of the wave between connection points 52 is free to move without applying a stress to longitudinal members 46.

During circumferential expansion, the flexible circumferential bands 48 straighten, thereby taking up the stress of expansion without applying an undue stress on longitudinal members 46. It will be understood that while the circumferential bands are described as wave shaped, circumferential bands that are not true wave shapes, such as where the pattern differs between two adjacent longitudinal members 46, are also contemplated by the present invention.

It is also contemplated that the circumferential bands may be composed of a plurality of closed loops. Each loop is attached to other loops in the band at opposite points on the loop with approximately equal length in both loop segments between the attachment points. The adjacent loops may be attached to each other directly at attachment points or by a line extending between the attachment points of the loops. Before expansion, the opposite attachment points of a loop will be close together. As the stent expands, and the loop deforms, the attachment points will move apart. The loops may be oval, rectangular, diamond or other closed shapes, connected to form a circumferential band that can be expanded.

Longitudinal members will connect to circumferential bands containing closed loops at the attachment point between the loops or on the line that attaches the loops.

As one skilled in the art of making stents will realize, the exact number of longitudinal members 46 and the number of flexible circumferential bands 48 along the length of the stent will depend upon a number of factors, including the circumference, length and expansion desired for the stent and similar factors. For example, Fig. 5 shows six circumferential bands 48 which are preferable in a stent of about 18 mm in length that can accommodate a three-fold expansion.

The size and configuration of flexible circumferential bands 48 will depend primarily on the amount of circumferential expansion and strength desired. Flexible circumferential bands 48 having waves or loops of greater height will allow greater expansion. However, bands having high waves or loops will be weaker than bands having shorter waves and/or loops. Stents composed of shorter height bands will also be stronger because more bands will fit in a stent of a given length. In addition, the stent is preferably configured to allow the desired expansion without excessive deformation of flexible circumferential bands 48. In normal use, a balloon-expanded stent is expanded to about 2 to 3 times its original diameter.

The pattern herein described, including the embodiment depicted in Fig. 5, adds many advantages over prior lattice stent patterns. As described above, an expansion of the circumference of the stent will not result in a shortening of the stent. Further, the stent provides a uniform support for the vessel into which it is inserted. Multiple longitudinal members prevent gaps from forming between the circumferential bands while the loops in the longitudinal members maintain flexibility. Other advantages will be observed by those skilled in the art.

The stent pattern of the present invention can also readily be made from any one of the methods known in the art and/or described above. It will be readily apparent to one skilled in the plating arts that the stent pattern depicted in Fig. 5 can be produced by the same process used to produce the stent pattern of Figs. 2 and 3 by varying only the pattern that is exposed. However, the stent pattern depicted in Fig. 5 has a functional advantage over that depicted in Figs. 2 and 3 in that a stent formed with the stent pattern of Fig. 5 will not shorten as the circumference expands and has increased longitudinal flexibility. Further, it will be apparent that the stent pattern of Fig. 5 can be produced as an electroformed gold stent which can be activated by thermal neutrons as described below.

Development of the exposed photoresist is accomplished by passing the exposed resist-coated mandrel through a developer solution. The developer solution may readily be applied either as a spray or a dip. The type of developer solution and process time depends upon the particular photoresist selected. Generally stated, there are a large number of liquid photoresist coatings and related developers available which may be utilized in the present invention.

References to plating herein are to various established electroplating techniques and substances that may be employed in this invention. As is known to one skilled in the plating arts, plated metal thickness is proportional to time in the plating bath and plating electric current. Plating current may be manually or automatically adjusted to control the desired stent thickness. In a continuous mode process an appropriate thickness control system is used to monitor the plated thickness and automatically adjust the plating current. Alternating or pulsed plating currents may be used to improve or modify the deposit properties. If an alloy is being deposited, the alloy composition is a function of the current density. Time-based changes in the current density can produce radial microscopic changes in alloy composition, which may be desirable to meet various strength and corrosion resistance requirements. Various alloys have characteristics which are desirable for stents. For example, high gold-content alloys can be produced by electroplating techniques. Such alloys can have high strength and are essentially as inert as gold. Therefore, these alloys also are expected to be biocompatible.

After plating, the mandrel is dissolved in an appropriate enchant. For example, nitric acid or a ferric chloride solution is suitable for removing copper from gold stents and sodium hydroxide solution is suitable for removing aluminum from nickel stents. Various other etching solutions are available to one experienced in the electroplating arts for various mandrel and stent material combinations.

When the mandrel material dissolves, the individual stent may be collected in a variety of fashions such as in a basket contained in the enchant tank, or onto a moving belt. The completed stents preferably are rinsed to remove etchant solution. Following mandrel removal the stents can be crimped to smaller diameter and can be neutron activated if formed of an appropriate metal, as discussed below.

In one embodiment of the present invention, the completed stent is comprised of a metal that may be transformed into a beta emitter by direct exposure to thermal neutrons. Insofar as angioplasty stents will be permanently implanted and in intimate contact with the

artery wall, the use of low level beta emitting stents is ideal. However, a high intensity beta emitter may be desired for other purposes, for example treating cancerous tumors. The low level beta emitting stent of the present invention will provide a uniform low therapeutic dose of radiation to the artery wall with minimum damage to deeper surrounding tissue. The radioactive material of the stent will have a half-life sufficient to provide radiation to the artery during the healing process but not long beyond. When used with certain metals, including gold, a characteristic gamma emission accompanies the beta emission. This low level gamma emission generally can be tolerated by the body and generally will not significantly damage surrounding tissue or otherwise significantly interfere with the advantages of the present invention.

Generally, any biocompatible metal having an acceptable half-life that can be transformed into a beta emitter by exposure to thermal neutrons can be used to form the stent of the present invention. Preferably, an electroplated gold stent is used, wherein the gold comprising the stent is neutron activated from natural Au 197 to the beta and gamma-emitting Au198 radioactive isotope. Preferably the electroformed gold stent is formed from a high purity neutral cyanide gold plating bath containing gold such as $KAu(CN)_2$. Typically the plating solution will also contain a phosphate buffer and operate at a pH of about 5.5 to about 8.0 and a temperature of about 50 to about 70° C. However, other high purity gold plating baths or high gold alloy baths may be used. Although Au198 is the preferred isotope, neutron activation to Au199 is also consistent with the present invention. Unless an extremely high flux level or exposure time is utilized, nearly all of the radioactive nuclei will be Au198, with a very small number being activated to Au199.

Pure gold is not a standard material for stents. Most stents are stainless steel and most attempts to produce radioactive stents have, therefore, been directed to stainless steel stents. However, gold exhibits several properties that contribute to its usefulness in the present invention. For example, gold exists in nature as a pure stable Au197 isotope, unlike the stainless steel used in existing radioactive stents, which is an alloy of several elements, with each element existing as a variety of isotopes. Further, gold has a large thermal neutron absorption cross-section of 98.8 barns, making it ideal for thermal neutron activation to a beta-emitting stent. For Au198, approximately 98.9% of the beta particles carry a maximum energy of about 0.961 MeV followed by a 0.412 MeV gamma emission.

Other properties of the Au198 also contribute to the usefulness of gold in the radioactive stents of the present invention. Au198 has a half-life of 2.691 days. The half-life

is short enough to permit decay in a reasonable amount of time for therapeutic purposes, but is long enough to allow time for transport and storage before insertion into the body and to provide sufficient radiation to the artery during the healing process. Other beneficial properties of gold include its high degree of biocompatibility, process flexibility, and radio-opacity.

Although the preferred embodiment is directed to an electroformed gold stent, the present invention also contemplates the thermal neutron activation of gold-plated stents and gold stents formed by laser-cutting gold tubes and welding gold wires. In addition, other metals that are capable of thermal neutron activation and have a half-life short enough to permit decay in a reasonable amount of time for therapeutic purposes but long enough to provide sufficient radiation to the artery during the healing process may be utilized consistent with the present invention.

The precise therapeutic radiation activity level is specific to the patient and condition being treated and is generally determined based on prior data for the condition being treated or for similar conditions. Typically, at the time of insertion into the patient, the radioactive stent will have a radiation activity level preferably between about 1 and about 500 μCi, more preferably from about 30 to about 40 μCi. Such levels generally are considered suitable therapeutic levels. The activity level of the stent will decrease during shipment and storage due to radioactive decay. Thus, if the stent will not be used immediately, the stent preferably will be activated initially to a level high enough to account for radioactive decay during shipment and storage. Further, if the activity level of the stents decrease below a suitable therapeutic level during shipment and storage, the stent can be reactivated. Insofar as thermal neutron activation can deliver stents at almost any activity from 0 to over 1,000 times higher than conventional radioactive stents, thermal activation is an ideal method for producing radioactive stents.

In a preferred process of forming the thermal neutron-activated gold stents of the present invention, a gold stent is activated in a fission reactor, for example a research reactor, or other source of thermal neutrons to achieve the desired activity level. The resulting activity level for Au198 is proportional to the product of exposure time and thermal neutron flux. Preferably, the stent is placed in a fission reactor in which the neutron flux is moderate, for example between about 1×10^{12} and about 5×10^{13} neutrons per second per cm^2, or more preferably about 1×10^{13} neutrons per second per cm^2. At such a neutron flux levels, the stent typically would be removed from the reactor after about four seconds. In addition, exposure

to a neutron flux of 4×10^{13} neutrons per second per cm^2 for one second is also consistent with the present invention. Alternatively, the stent may be exposed to a lower neutron flux level for a longer period of time to reach the desired level of radiation, as can be readily calculated by one skilled in the art. In other embodiments of the invention, neutrons may be generated electrically by accelerating a beam of electrons into a deuterium/tritium target, by exposing beryllium to alpha particles, or may be obtained from isotope neutron sources, such as Cf 252.

Neutron-activated gold stents are preferably produced by activation of a large quantity of stents in a single exposure to thermal neutrons. Thus, the cost to neutron-activate the stents may be held to a minimum, allowing the stents of the present invention to be produced in commercial quantities. Stents may also be neutron activated after mounting on a balloon catheter.

EXAMPLE 1

An experiment was conducted to demonstrate that gold electroformed stents could be made radioactive by neutron activation. Stents formed in three different gold plating baths were activated to determine if any differences could be measured due to possible differences in trace elements contained in the deposits from different baths.

Three gold plating solutions manufactured by Technic, Inc. of Providence, Rhode Island were used. They were Orotemp 24, Orotemp 24C, and Orotemp 24T. Orotemp 24T contains thallium as a grain refiner. Three electroformed stents, one from each bath, were neutron activated by the following process.

Each stent was washed individually in 1 N HCL, rinsed four times with deionized water, and then dried with acetone. The samples were weighed and encapsulated in cleaned polyethylene vials. The samples and vials were then irradiated for one second in a flux trap pool type, light-water moderated and cooled, beryllium-reflected reactor, at the University of Missouri in Columbia, Missouri, in Row 2 p-tube position. The thermal neutron flux was measured to be 4×10^{13} neutrons per second per cm^2. The samples were removed from their encapsulation and first assayed in a dose calibrator, indicating 30-40 μCi of Au198 per stent, which weighed about 40-60 mg each. This is approximately as expected from theory. One day following the test activation, the three samples plus a background were counted 15 minutes each on a detector and multichannel analyzer. All peaks found were consistent with Au198 or the known background. Subsequent counts 19 days after activation for 30 minutes each revealed only Au198 peaks.

The experiment demonstrates that gold stents can be neutron activated to levels of 30 μCi, which is equivalent to what others have used for brachytherapy. Also, no radiation was detected from other elements, even after the Au198 was allowed to decay through several half-lives, indicating that electroformed gold is sufficiently pure that no impurities exist to produce undesirable or long half-life radiation.

EXAMPLE 2

For the stent pattern depicted in Fig. 5, the circumference of the stent can expand form the Original Circumference, C_0, to a Maximum Expanded Circumference, C_E, calculated as follows:

$C_E = C_O + (2)(N)(H)$ where

N = the Number of loops/wave peaks in a flexible circumferential band 48 and

H = the Height of the loop/wave peak

For the design shown in Fig. 5

$C_O = 0.495$ cm (0.195 inch)

N = 5

H = 0.196 cm (0.077 inch)

Therefore $C_E = 0.495 + (2)(5)(0.196) = 2.455$ cm (0.965 inch)

The ratio of $C_E/C_O = 2.455$ cm / 0.495 cm = 4.96 cm

Thus, the stent shown in Fig. 5 could expand to almost 5 times its original circumference, from .495 cm to 2.455 cm. The stent pattern is designed to accommodate a three fold expansion without excessive deformation of the flexible circumferential bands and to provide adequately spaced supports to prevent prolapse of tissue. At the full five fold expansion, the loops or waves in the flexible circumferential band will stretch to approximately a straight band around the circumference of the stent.

Computer modeling using finite element analysis and physical measurements on stents with the pattern depicted in Fig. 5 show a reduction in length of less than one percent when the stent is expanded to about 2.5 times its original circumference.

From the foregoing, it will be seen that this invention is well-suited to attain all the ends and objects set forth herein together with other advantages which are obvious and inherent to the invention.

It will be understood that certain features and combinations are of utility and may be employed without reference to other features and combinations. This is contemplated and within the scope of the invention.

Since many possible embodiments may be made of the invention without departing from the scope thereof, it is to be understood that all matters herein set forth or shown in the accompanying drawings are to be interpreted as illustrative and not in a limiting sense.

CLAIMS

I claim:

1. A radioactive stent comprising a stent which has been made radioactive through exposure to thermal neutrons.

2. The radioactive stent as claimed in claim 1, wherein said stent is comprised of gold.

3. The radioactive stent as claimed in claim 2, wherein said stent emits beta radiation at a therapeutic level.

4. The radioactive stent as claimed in claim 3, wherein said stent has a radioactivity level ranging between about 1 and about 500 μCi when inserted into a patient.

5. The radioactive stent as claimed in claim 4, wherein said stent has a radioactivity level ranging between about 30 and about 40 μCi when inserted into a patient.

6. The radioactive stent as claimed in claim 1 wherein said stent consists essentially of gold.

7. The radioactive stent as claimed in claim 1 wherein said stent has a radioactivity level ranging between about 1 and about 500 μCi when inserted into a patient.

8. A process for forming a radioactive gold stent, comprising:

exposing a gold stent to thermal neutrons.

9. The product of the process as claimed in claim 8.

10. The process for forming a radioactive gold stent as claimed in claim 8, wherein said exposing step comprises:

placing said stent is a fission reactor; and

removing said stent from said reactor.

11. The product of the process as claimed in claim 10.

12. The process for forming a radioactive gold stent as claimed in claim 10, wherein said placing step includes:

placing said stent in said reactor for about 4 seconds, wherein said neutron flux in said reactor is between about 1×10^{12} and about 5×10^{13} neutrons per second per cm^2.

13. The process of forming a radioactive gold stent as claimed in claim 10, wherein said placing step includes:

placing said stent in said reactor for about one second wherein said neutron flux in said reactor is about 4×10^{13} neutrons per second per cm^2.

14. A process for producing a stent comprising the steps of:

coating a mandrel with a resist;

exposing portions of said resist to a light pattern so as to form a stent pattern on said mandrel in said resist;

plating metal onto said mandrel in said stent pattern so as to form a stent;

dissolving said resist and said mandrel; and

exposing said stent to thermal neutrons.

15. The process as claimed in claim 14 wherein said plating step consists essentially of plating gold.

16. The product of the process as claimed in claim 14.

17. The product of the process as claimed in claim 15.

18. A stent pattern for an essentially cylindrical-shaped stent, the pattern comprising:

at least one longitudinal member extending parallel the longitudinal axis of said stent, said longitudinal member configured to resist extension and contraction in the direction along said stent axis; and

a plurality of flexible circumferential bands connected to said longitudinal member, said flexible circumferential bands configured to deform when the circumference of said stent is expanded, allowing expansion of the circumference of said stent without a corresponding contraction of said longitudinal members in the direction along said stent axis.

19. The stent pattern as claimed in claim 18 wherein said stent pattern comprises one longitudinal member and said flexible circumferential bands connect to said longitudinal member at one point per band.

20. The stent pattern as claimed in claim 19 wherein said flexible circumferential bands are wave-shaped and the wave shape is selected from the group consisting of sinusoidal, saw-tooth, square and rectangular waves.

21. The stent pattern as claimed in claim 18 wherein said stent pattern comprises at least two parallel longitudinal members wherein a particular flexible circumferential band is connected to each said longitudinal member at one connection point per member, and each said connection point for each such particular band is located about an equivalent distance along said stent axis.

22. The stent pattern as claimed in claim 21 wherein said flexible circumferential bands are wave-shaped and the wave shape is selected from the group consisting of sinusoidal, saw-tooth, and rectangular waves.

23. The stent pattern as claimed in claim 21 wherein each said flexible circumferential band forms a wave pattern and all said connection points on each particular band are located an integer number of wavelengths apart.

24. The stent pattern as claimed in claim 23 wherein said connection points on each particular band are located at a wave peak.

25. The stent pattern as claimed in claim 21 wherein said flexible circumferential bands each comprise closed loops located between adjacent longitudinal members.

26. The stent pattern as claimed in claim 18 wherein said stent pattern is produced by coating a mandrel with a resist;

exposing portions of said resist to a light pattern so as to form said stent pattern;

plating metal onto said mandrel in said stent pattern so as to form a stent; and

dissolving said mandrel.

27. The stent as claimed in claim 26 wherein said metal is gold and said stent is made radioactive by exposure to thermal neutrons.

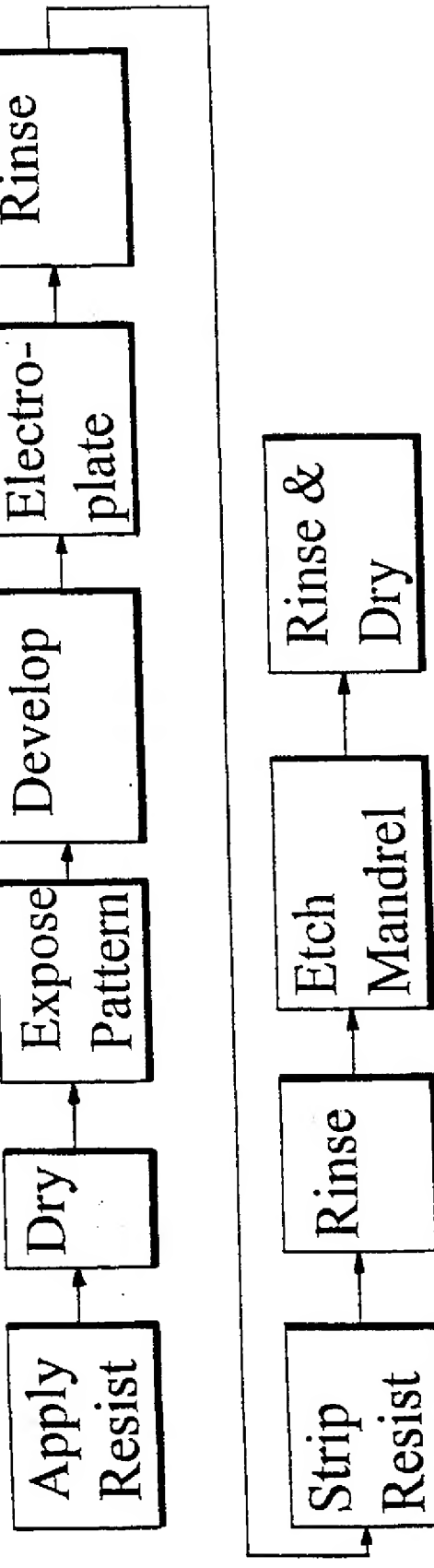
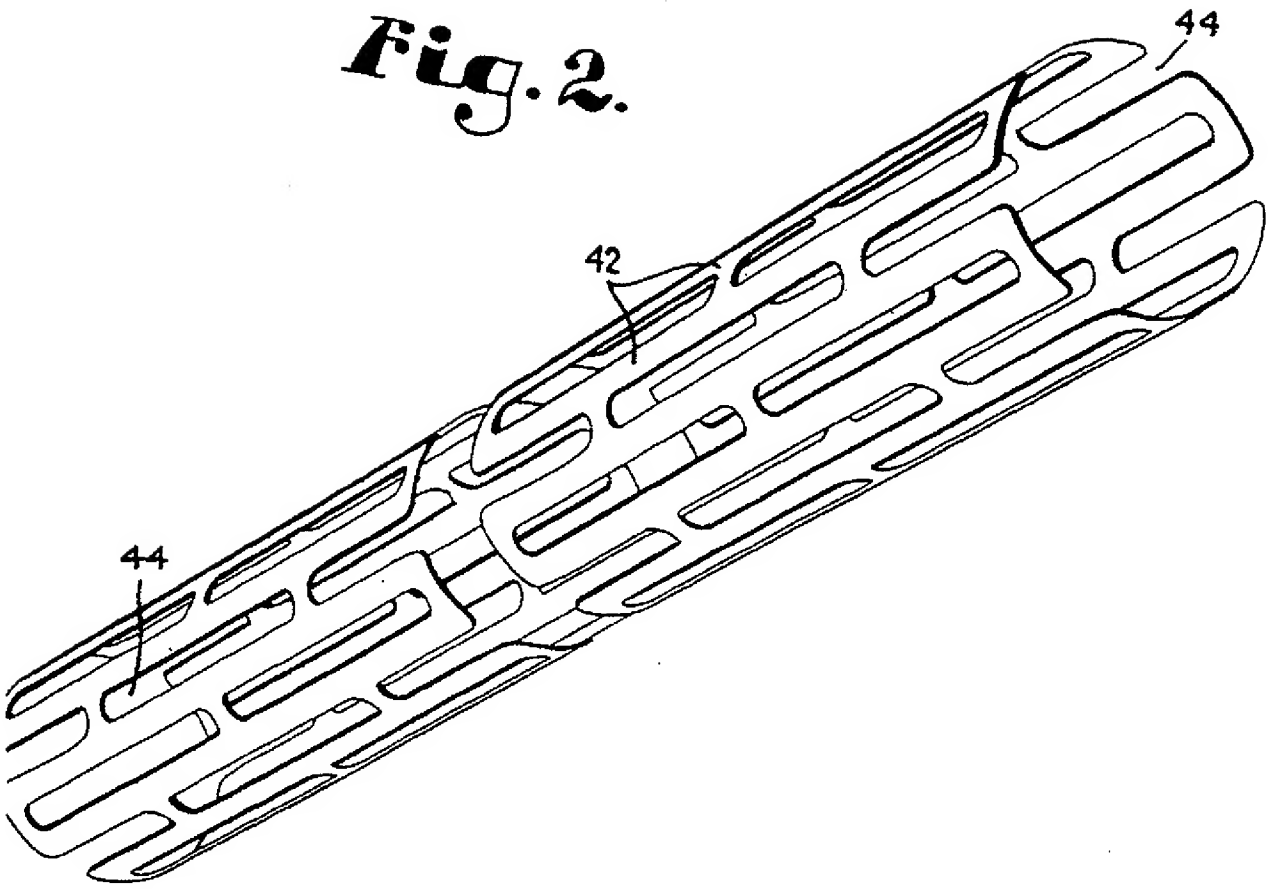

Apply Resist
Dry
Expose Pattern
Develop
Electro-plate
Rinse
Strip Resist
Rinse
Etch Mandrel
Rinse & Dry

Fig. 1.

Fig. 2.



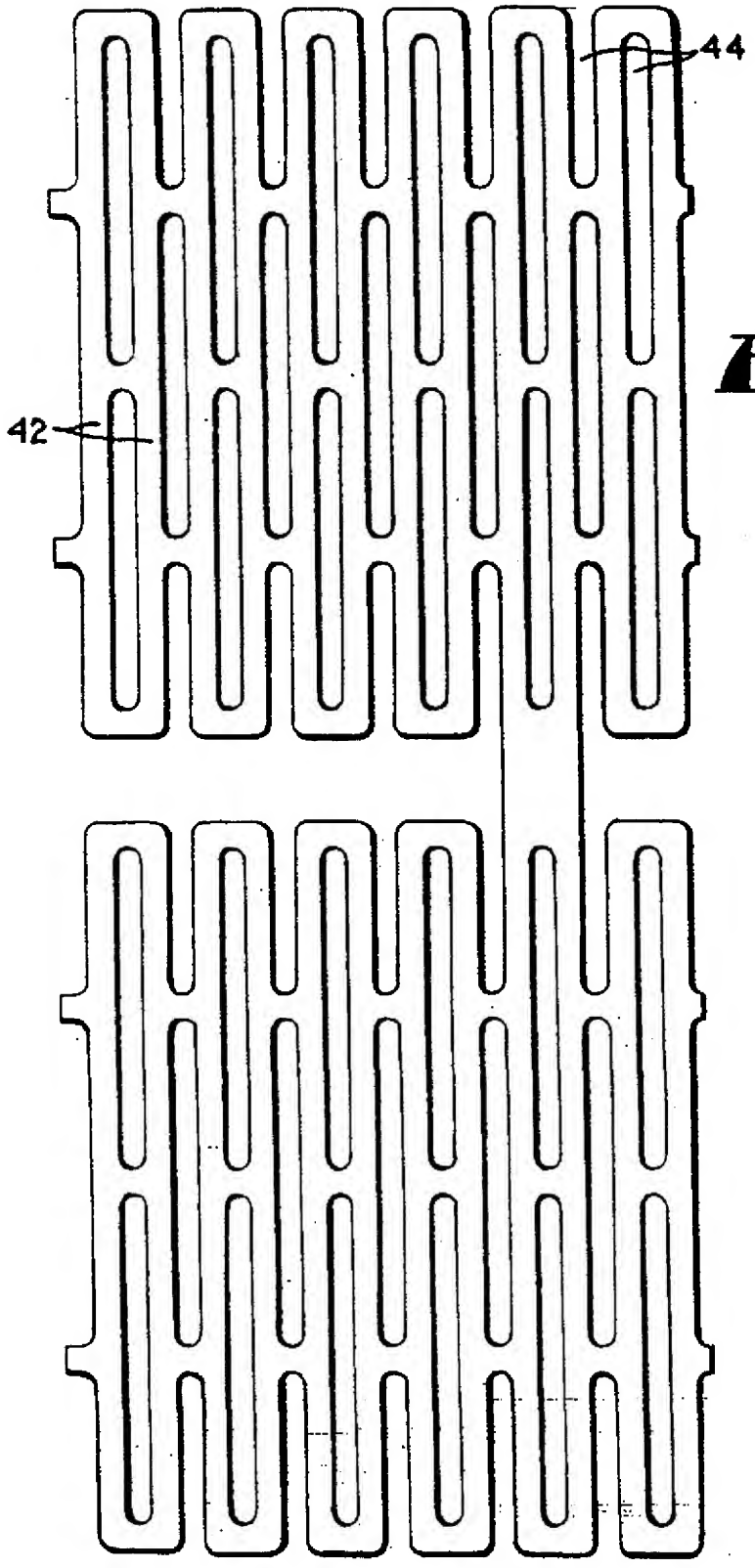


Fig.3.

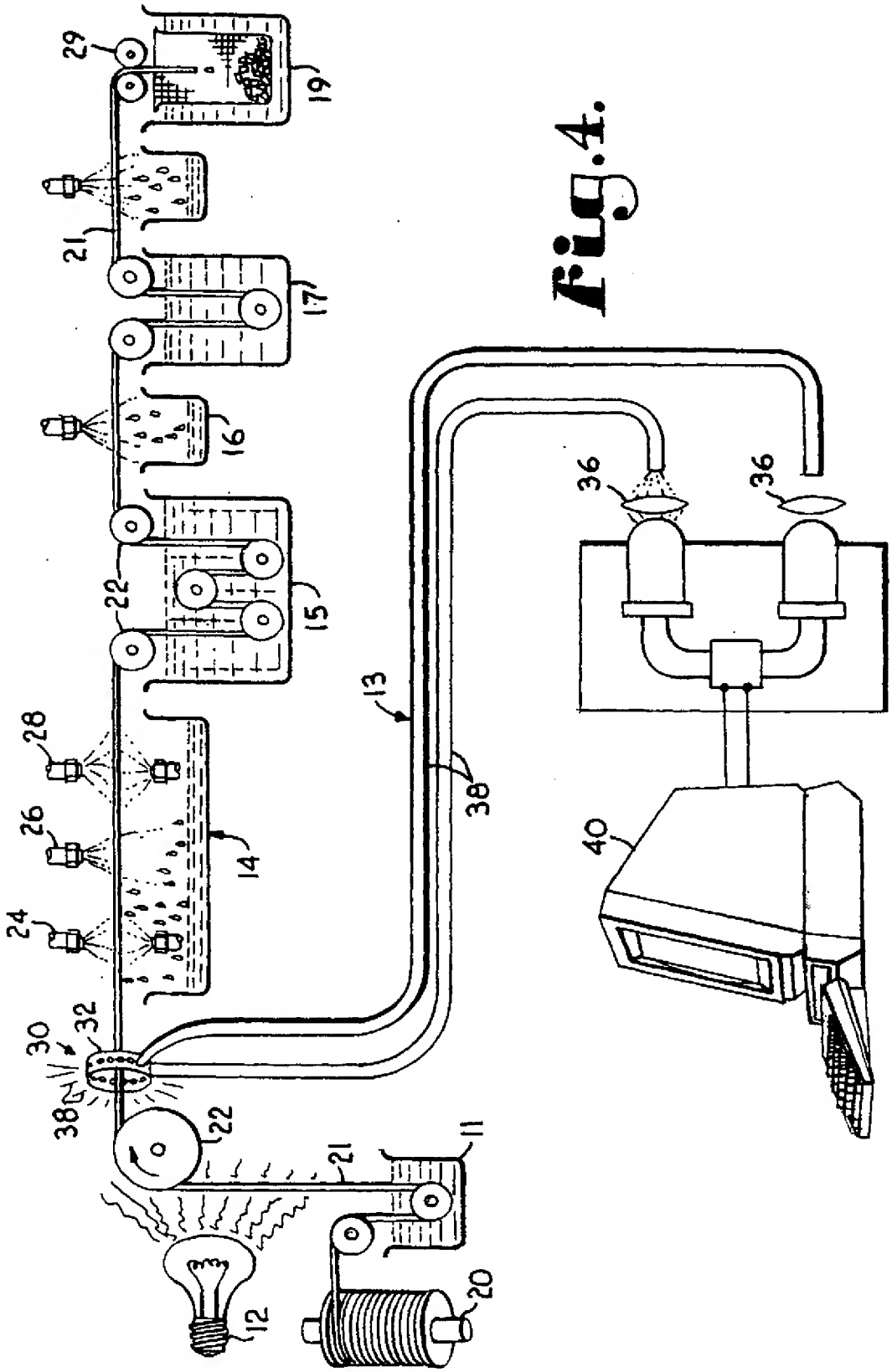


Fig.4.

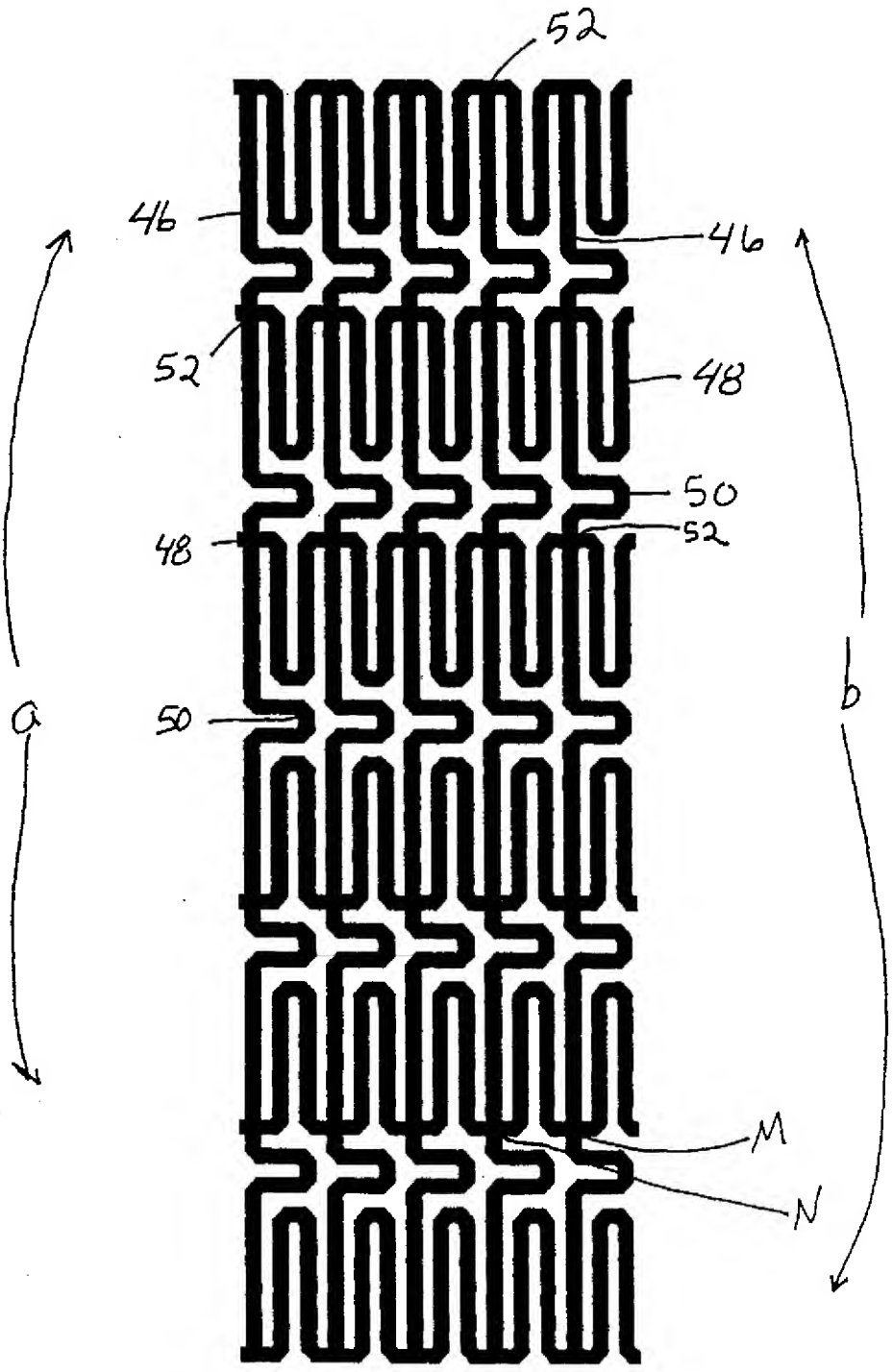


Fig. 5